# IAP20 REGISTRATION 19 DEC 2005 PATENT APPLICATION

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q92060

Megumi KUMEMURA, et al

Appln. No.: National Stage of PCT/JP2004/009212

Confirmation No.: Unknown Group Art Unit: Unknown

Filed: December 19, 2005 Examiner: Unknown

For: COMPOSITION FOR LOWERING SERUM URIC ACID LEVEL

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

A copy of an International Search Report in a counterpart application is submitted herewith. The USPTO should receive copies of the references cited in the International Search Report from the International Bureau. Applicant will furnish any missing references upon request.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after

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INFORMATION DISCLOSURE STATEMENT

Appln. No.: National Stage of PCT/JP2004/009212

Attorney Docket No. Q92060

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filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of a Communication from a foreign patent office in a counterpart application citing such documents (International Search Report for PCT/JP2004/009212 dated October 19, 2004), together with an English-language version (if not already included) of at least that portion of the Communication indicating the degree of relevance found by the foreign patent office.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

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Date: December 19, 2005

WASHINGTON OFFICE 23373
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MODIFIED PTO/SB/08 A & B (06-03)

Substitute for Form 1449 A & B/PTO

### **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

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| Application Number  National Stage of 27  ROW/JP2004/009212 |                   |  |  |  |  |
| Confirmation Number   | Unknown           |  |  |  |  |
| Filing Date   | December 19, 2005 |  |  |  |  |
| First Named Inventor  | Megumi KUMEMURA   |  |  |  |  |
| Art Unit  | Unknown           |  |  |  |  |
| Examiner Name   |                   |  |  |  |  |
| Attorney Docket Number                                      | Q92060            |  |  |  |  |

| <u> </u>              |              |                 | U.S.                                    | PATENT DOCUM                   | ENTS  |
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|                       |              | Document Number |   |                                |   |
| Examiner<br>Initials* | Cite<br>No.1 | Number          | Kind<br>Code <sup>2</sup><br>(if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
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|           | FOREIGN PATENT DOCUMENTS |                              |                     |                                   |                     |   |                          |  |  |
|-----------|--------------------------|------------------------------|---------------------|-----------------------------------|---------------------|---|--------------------------|--|--|
| Examiner  | Cite                     | Foreign Patent Document      |                     | Publication Date                  | Name of Potentes or |   |                          |  |  |
| Initials* | No.1                     | Country<br>Code <sup>3</sup> | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) | MM-DD-YYYY          | Name of Patentee or Applicant of Cited Document | Translation <sup>6</sup> |  |  |
|           |                          | JP                           | 2003-500451         | Α                                 | 01/07/2003          | VSL PHARMA LTD.                                 |                          |  |  |
|           |                          | WO                           | 02/91833            | A1                                | 11/21/2002          | KIBOW BIOTECH INC.                              |                          |  |  |
|           | _                        | JP                           | 2004-161618         | Α                                 | 06/10/2004          | KIRIN BREWERY CO., LTD.                         |                          |  |  |
|           |                          | JP                           | 2001-501621         | Α                                 | 02/06/2001          | PHARMANEX INC.                                  |                          |  |  |
|           |                          | JP                           | 8-163983            | Α                                 | 06/25/1996          | KANEBO, LTD.                                    |                          |  |  |
|           |                          | JP                           | 11-318351           | A                                 | 11/24/1999          | TAKARA SHUZO KABUSHIKI<br>KAISHA                |                          |  |  |
|           |                          |                              |                     |                                   |                     |   |                          |  |  |

|                       |              | NON PATENT LITERATURE DOCUMENTS   |                          |
|-----------------------|--------------|---|--------------------------|
| Examiner<br>Initials* | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.                    | Translation <sup>6</sup> |
|                       |              | Takeshi IKENAGA, ET AL, "TAKAI PURINE NUCLEOSIDE TAISHANO o YUSURU NYUSANKIN NO SHOKUJISEI KO NYOSAN KESSHO MODEL RAT NO KECCHU NYOSANCHI NI OYOBOSU EIKYO", NIPPON EIYO SHOKURYO GAKKAI SOKAI KOEN YOSHISHU, Vol. 58th, April 1, 2004, page 318, 31-4p                             |                          |
|                       |              | Jun OGAWA, ET AL, "PURINE NUCLEOSIDE TAISHA NI EIKYO o OYOBOSU NYUSANKIN NO TANSAKU", NIPPON NOGEI KAGAKUKAI 2004 NENDO (HEISEI 16 NENDO) KOEN YOSHISHU, March 5, 2004, page 197, 3A15a06   |                          |
|                       |              | Takeshi IKENAGA, ET AL, "SHOKUJISEI NYOSAN KESSHO MODEL RAT NO KECCHU<br>NYOSANCHI NI OYOBOSU NYUSANKIN NO EIKYO", NIPPON NOGEI KAGAKUKAI 2004<br>NENDO (HEISEI 16 NENDO) KOEN YOSHISHU", March 5, 2004, page 197 3A15a07   |                          |
|                       |              | C. CAMPIERI, ET AL, "REDUCTION OF OXALURIA AFTER AN ORAL COURSE OF LACTIC ACID BACTERIA AT HIGH CONCENTRATION", KIDNEY INT., Vol. 60, No. 3, 2001, pages 1097-1105  |                          |
|                       |              | S. HOKAMA, ET AL, "OXALATE-DEGRADING ENTEROCOCCUS FAECALIS", MICROBIOL. IMMUNOL., Vol. 44, No. 4, 2000, pages 235-240   |                          |
|                       |              | DATABASE EMBASE ON STN, (2004) ABSTRACT NO. 2004081271 & J. KOZLOWSKI, ET AL, "THE INFLUENCE OF THE ORAL ADMINISTRATION OF LACTIC ACID BACTERIA ON THE OXALURIA IN THE CHILDREN WITH CALCIUM-OXALATE NEPHROLITHIASIS", PRZEGLAD PEDIATRYCZNY, Vol. 33, No. 4, pages 313-316, (2003) |                          |

| Examiner Signature | Date Considered |
|--------------------|-----------------|

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Q92060

**Attorney Docket Number** 

#### Complete if Known Substitute for Form 1449 A & B/PTO National Stage of PCIMP2004/0092122 75 **Application Number** INFORMATION DISCLOSURE **Confirmation Number** Unknown STATEMENT BY APPLICANT Filing Date December 19, 2005 First Named Inventor Megumi KUMEMURA (use as many sheets as necessary) Art Unit Unknown **Examiner Name**

|                       | -                        |                 | U.S.                                    | PATENT DOCUM                   | ENTS  |
|-----------------------|--------------------------|-----------------|---|--------------------------------|---|
|                       | •                        | Document Number |   |                                |   |
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Number          | Kind<br>Code <sup>2</sup><br>(if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document |
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|           | FOREIGN PATENT DOCUMENTS |                              |                     |                                   |                     |                             |                          |  |
|-----------|--------------------------|------------------------------|---------------------|-----------------------------------|---------------------|-----------------------------|--------------------------|--|
| Examiner  | Cite                     | Cite Foreign Patent Document |                     | Publication Date                  | Name of Patentee or |                             |                          |  |
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|                       |              | NON PATENT LITERATURE DOCUMENTS  |                          |
|-----------------------|--------------|--|--------------------------|
| Examiner<br>Initials* | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.                 | Translation <sup>6</sup> |
|                       |              | DATABASE CAPLUS ON STN, (1962), No. 57:71652 & T. PORSCHE, ET AL, "THE USE OF URIC   |                          |
|                       |              | ACID BY SACCHAROMYCES", ACAD. REP. POPULARE ROMINE, BAZA CERCETARI STIINT  |                          |
|                       |              | TIMISOARA, STUDII CERCETARI STIINTE CHIM., Vol. 8, No. 1 to 2, pages 181-183, (1961)   |                          |
|                       |              | DATABASE CAPLUS ON STN, (1986), No. 104:105897 & W. J. MIDDELHOVEN, ET AL, "YEAST  |                          |
|                       |              | SPECIES UTILIZING URIC ACID, ADENINE, N-ALKYLAMINES OR DIAMINES AS SOLE  |                          |
| l                     |              | SOURCE OF CARB ON AND ENERGY", ANTONIE VAN LEEUWENHOEK, Vol. 51, No. 3,  |                          |
| <del></del>           |              | pages 289 to 301, (1985)   |                          |
|                       |              | DATABASE CAPLUS ON STN, (1979) No. 90:20791 & H. ONISHI, ET AL, "SCREENING AND   |                          |
|                       | _            | CULTIVATION OF EXCELLENT URIC ACID-UTILIZABLE YEASTS", NIPPON NOGEI KAGAKU KAISHI, Vol. 52, No. 8, pages 317-321, (1978)   |                          |
|                       |              | DATABASE BIOSIS ON STN, (1984), No. 1984:261891 & W. J. MIDDELHOVE, ET AL, "GROWTH OF CANDIDA-FAMATA AND TRICHOSPORON-CUTANEUM ON URIC ACID AS THE SOURCE OF CARBON AND ENERGY A HITHERTO UNKNOWN PROPERTY OF YEASTS", J. MICROBIOL., Vol. 49, No. 4 to 5, pages 361-368, (1983) |                          |
|                       | -            | JUN OGAWA, ET AL, "KO NYOSAN KESSHO YOBO NI YUKO NA SAIKIN PURINE<br>NUCLEOSIDASE NO SHO SEISHITSU", NIPPON NOGEI KAGAKU KAISHI, Vol. 75 SPECIAL<br>EXTRA ISSUE, 2001, page 366, 3Y6a10  |                          |
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